**REMARKS**

Claims 1-56 are pending. Claim 57 is added. Applicant submits that the amendments introduce no new matter. Support for the amendments can be found throughout the application as originally filed (e.g. see [0053] of Published Application No. 2004-0138630).

Applicant makes these claim amendments and cancellations without prejudice. Also, applicant disagrees with all rejections and makes these claim changes only to expedite prosecution and move to allowance as soon as possible.

2. 35 U.S.C. §102 Rejections

Claims 1-9, 11, 18-29, 35, and 38-56 are rejected under 35 U.S.C. §102(e) in view of Berke (US 6,336,917).

Applicants respectfully traverse.

Applicants' independent claim 1 recites a device for the delivery of a substance to the eye comprising a housing for holding the substance, at least one outlet port through which the substance is delivered from the device to the eye, and a non-aerosol, non-electric delivery mechanism, whereby the substance is delivered to the eye in the form of a spray or mist.

Applicants' independent claim 2 recites a device for the delivery of an artificial tears or demulcent composition to the eye comprising a housing for holding the substance, at least one outlet port through which the substance is delivered from the device to the eye, and a non-aerosol, non-electric delivery mechanism, whereby the substance is delivered to the eye in the form of a spray or mist.

Applicants' independent claim 49 recites a method for the delivery of a substance to the ocular surface of a patient comprising providing a non-aerosol, non-electric delivery device housing the substance, positioning the patient's head such that the line of sight is in a generally

horizontal direction, positioning device in front of the eye in the line of sight, and delivering the substance to the eye as a spray or mist in a generally horizontal direction.

Applicants' independent claim 50 recites method to minimize risk of infection when a substance is delivered to the eye comprising providing a non-aerosol, non-electric delivery device housing the substance, holding the device a distance away from the eye without contacting the eye, and delivering the substance to the eye in the form of a spray or mist.

Berke describes a metered spray eye mist apparatus for administering a metered amount of medication to the eye (see col. 1, lines 7-9). As set out, the metered spray device is "similar to an inhaler used by asthmatics in that it dispenses a metered spray of medication or fluid by applying pressure to a medicine vial disposed within the dispenser" (col. 3, lines 57-61).

Inhalers that dispense metered sprays of medication to asthmatics are called metered-dose inhalers (MDIs). Metered dose inhalers are well known, and are pressurized devices that use propellants to deliver a metered amount of medication to the lungs of a patient. A canister containing the aerosol propellant and the medication is actuated by a metering dose valve within an actuating stem. As the actuating stem is pushed upwards into the canister, the aerosolized medication is expelled from the canister.

Berke, thus, describes a metered spray device in the form of an MDI that uses propellants to deliver the metered amount of medication to the eye. As shown in the Figures, a medicine vial 60 housing the medicine and propellant is housed within the medicine dispenser body 52 in a vertical position with a nozzle extending downwards from the bottom of the vial 60. As the nozzle is depressed upwards into the vial 60, a metered amount of medicine is released (see e.g. FIG. 4, col. 6, lines 5-48).

The Office asserts that Berke is not necessarily a conventional metered dose dispenser and that there is no teaching and/or disclosure by the reference that aerosol is used to disperse the medication (Office action at page 7). Applicants respectfully disagree. According to Berke's

description and Figures, the device must necessarily be in the form of a MDI, and the vial 60 must necessarily house a propellant to drive the medicine in the vial 60 out of the vial through the nozzle in the form of a metered spray. In particular, a medicine housed in the vial 60 (see FIG. 4) would not be capable of being delivered from the vial 60 via the downward extending nozzle in the form of a metered mist in the absence of a propellant given the configuration of the vial 60 and nozzle and the specific teaching of Burke.

Thus, Berke at least fails to teach or suggest a method or device for delivering a substance in the form of a spray or mist, wherein the device has a non-aerosol, non-electric delivery mechanism, as required by independent claims 1, 2, 49, and 50. Berke further at least fails to teach or suggest a device for treating the eye comprising a housing holding one or more substances and being free of propellant, and a non-aerosol, non-electric delivery mechanism, whereby the substance is delivered to the eye in the form of a spray or mist, as required by independent claim 57.

Further, Berke at least fails to teach or suggest a method to minimize risk of infection when a substance is delivered to the eye comprising providing a non-aerosol, non-electric delivery device housing the substance and delivering the substance to the eye in the form of a spray or mist, as recited in Applicants ' claim 50. According to Berke, the device is specifically designed such that the inner housing 20 contacts the eyelid and surrounding eyeball, while the outer housing 30 contacts the skin over the bony orbit surrounding the eye (see col. 4, lines 56-67). Thus, Berke does not teach a method wherein the device is held a distance away from the eye without contacting the eye. Rather, Berke is specifically designed for such contact and is used so as to contact the eyelid, surrounding eyeball, and skin. Applicants respectfully submits that this method and contact described by Berke would, in fact, increase the risk of infection.

Accordingly, claims 1, 2, 49, 50, and 57 are not anticipated by Berke. Claims 3-48, and 51-56 depend from claims 1 and 2 and, thus, also are not anticipated by Berke. Reconsideration and withdrawal of the rejection is respectfully requested.

3. 35 U.S.C. §103 Rejections

Claims 10, 12-17 are rejected under 35 U.S.C. §103(a) in view of Berke (US 6,336,917).

Applicants respectfully traverse.

As set forth above, Berke at least fails to teach or suggest a method or device for delivering a substance in the form of a spray or mist, wherein the device has a non-aerosol, non-electric delivery mechanism. Berke further at least fails to teach or suggest a device for treating the eye comprising a housing holding one or more substances and being free of propellant, and a non-aerosol, non-electric delivery mechanism, whereby the substance is delivered to the eye in the form of a spray or mist.

Accordingly claims 1 and 2 are patentable over Berke. Claims 10, 12-17 depend from claims 1 and 2 and, likewise, are patentable over Berke. Reconsideration and withdrawal of the rejection is respectfully requested.

**CONCLUSION**

In view of the foregoing, applicant respectfully requests reconsideration, withdrawal of all grounds of rejection and objection, and allowance of claims 1-57 in due course. The Examiner is invited to contact applicant's undersigned representative by telephone at the number listed below to discuss any outstanding issues.

Respectfully submitted,

Date: 1/29/08

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